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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/708,870 | 11/08/2000 | Sean Farmer | 19374-509 (GND-09) | 2981 |

7590 12/20/2001

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EXAMINER

AFREMOVA, VERA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1651 | 7 |

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|-------------------------------|
| Office Action Summary | Application No. 09/708,870 | Applicant(s) Farmer |
| | Examiner Vera Afremova | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Sep 10, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-35 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-35 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 20) Other: _____

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DETAILED ACTION

Claims 1-35 are pending and subject to restriction requirement.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 7-11, 13-17 and 19-23, drawn to compositions with bacterial stains belonging to the genus of *Bacillus*, classified in class 435, subclass 252.5, for example.
- II. Claims 6, 12, 18 and 24, drawn to an extracellular product derived from bacterial composition with *Bacillus sp.* culture, classified in class 424, subclass 114, for example.
- III. Claims 25-30 and 33-35, drawn to a method for inhibiting pathogenic infection with bacterial stains belonging to the genus of *Bacillus*, classified in class 424, subclass 93.46, for example.
- IV. Claims 25-28, 31, 32 and 35, drawn to a method for inhibiting pathogenic infection with an extracellular product derived from bacterial compositions with *Bacillus sp.* culture, classified in class 424, subclass 114, for example.

The inventions are distinct, each from the other because of the following reasons:

The inventions of the Group I and the Group II are distinct because they are different products such as an isolated and viable bacterial strain belonging to the genus of *Bacillus* (Group I) and an extracellular product derived/purified from cells of a bacterial strain belonging to the

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genus of *Bacillus* (Group II). Thus, the components of the claimed products are distinct. And the components which are required for the Group I product are not required for the Group I product as claimed.

The inventions of the Group III and the Group IV are distinct because they are different methods which encompass the use of distinct products such as viable bacterial cells and extracellular product purified from bacterial cells. Thus, the active steps of the claimed methods are distinct. And the active steps and structural elements which are required for the Group III method of administration are not required for the Group IV method of administration.

Further, the inventions of the Groups I -IV are related as product (Groups I and II) and process of use (Groups III and IV). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a product such as a composition with an isolated bacterial strain belonging to the genus of *Bacillus* can be used for a preparation of yogurt [US 4,210,672]. And the methods of inhibiting bacterial infection can be practiced with a large variety of biotherapeutic agents including probiotics and antibiotics [Elmer et al.].

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by different classification). The search for each of the above

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inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the Invention of Group I would not necessarily anticipate or make obvious the other groups. For these reasons restriction for examination purposes is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR1.48(b) and by the fee required under 37 CFR1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova, Ph.D.

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December 12, 2001.

V.A.

SANDRA E. SAUCIER
PRIMARY EXAMINER

